

Substitute for form 1449A/PTO

**SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Complete if Known

U.S. Application No.	10/042,644
Filing or 371(c) date	January 8, 2002
First Named Inventor	Jacques F. BANCHEREAU
Group Art Unit	1646
Examiner Name	Chandra, Gyan

Sheet 1 of 5

Attorney Docket No: AGT.10006NP

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document
	7,179,465	02-20-2007	Benoit et al.
	7,087,726	08-08-2006	Chuntharapai et al.
	6,787,634	09-07-2004	Benoit et al.
	6,713,609	03-30-2004	Chuntharapai et al.
	6,475,983	11-05-2002	Eid et al.
	6,458,932	10-01-2002	Novick et al.
	6,333,032	12-25-2001	Skurkovich et al.
	6,136,309	10-24-2000	Novick et al.
	5,919,453	07-06-1999	Benoit et al.
	5,889,151	03-30-1999	Mogensen et al.
	5,886,153	03-23-1999	Mogensen et al.
	5,055,289	10-08-1991	Frincke et al.
	4,973,556	11-27-1990	Bove et al.
	4,902,618	02-20-1990	Berg
	4,474,754	10-02-1984	Shimizu et al.
	4,423,147	12-27-1983	Secher et al.
	US20070014724	01-18-2007	Witte et al.
	US20050013799	01-20-2005	Skurkovich et al.
	US20050013800	01-20-2005	Skurkovich et al.
	US20040191840	09-30-2004	Benoit et al.
	US20050013813	01-20-2005	Maroun

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	US20040132139	07-08-2004	Escary
	US20030147889	08-07-2003	Tovey
	US20030018174	01-23-2003	Kim et al.
	US20030166228	09-04-2003	Chuntharapai et al.
	US20030021764	01-30-2003	Maroun

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Abstract, Translation, English Language Equivalent or Search Report
	WO 06/037247	04-13-2006		
	WO 05/059106	06-30-2005		
	WO 04/094473	11-04-2004		
	EP 0 325 471 A1	07-26-1989		

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Abstract, Translation, English Language Equivalent or Search Report
	Alkan and Braun (1986) <i>Ciba Found. Symp.</i> 119: 264-278, entitled "Epitope Mapping of Human Recombinant Interferon alpha Molecules by Monoclonal Antibodies."	
	Baechler et al. (2003) <i>Proc. Nat'l. Acad. Sci. USA</i> 100(5): 2610-2615, entitled "Interferon-inducible gene expression signature in peripheral blood cells of patients with severe lupus."	
	Banchereau et al. (2004) <i>Immunity</i> 20(5): 539-50, entitled "Autoimmunity through cytokine-induced dendritic cell activation."	
	Båve et al. (2003) <i>J. Immunol.</i> 171: 3296-3302, entitled "FcγRIIa is expressed on natural IFN-α-producing cells (plasmacytoid dendritic cells) and is required for the IFN-α production induced by apoptotic cells combined with lupus IgG."	
	Berg (1984) <i>J. Interferon Res.</i> 4(4): 481-491, entitled "Identification, production, and characterization of murine monoclonal antibody (LO-22) recognizing 12 native species of human alpha interferon."	
	Björck (2004) <i>J. Immunol.</i> 172(9): 5396-5404, entitled "Dendritic cells exposed to herpes simplex virus <i>in vivo</i> do not produce IFN-alpha after rechallenge with virus <i>in vitro</i> and exhibit decreased T cell alloreactivity."	

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	Blanco <i>et al.</i> (2001) <i>Science</i> 294: 1540-1543, entitled "Induction of dendritic cell differentiation by IFN-alpha in systemic lupus erythematosus."	
	Blank <i>et al.</i> (1999) <i>Eur. J. Biochem.</i> 265(1): 11-19, entitled "Identification of a linear epitope of interferon-alpha 2b recognized by neutralizing monoclonal antibodies."	
	Blomberg <i>et al.</i> (2003) <i>Arthritis Rheum.</i> 48(9): 2524-32, entitled "Expression of the markers BDCA-2 and BDCA-4 and production of interferon-alpha by plasmacytoid dendritic cells in systemic lupus erythematosus."	
	Braun <i>et al.</i> (2003) <i>J. Autoimmun.</i> 20(1): 15-25, entitled "Type I interferon controls the onset and severity of autoimmune manifestations in lpr mice."	
	Chuntharapai <i>et al.</i> (2001) <i>Cytokine</i> 15(5): 250-60, entitled "Characterization and humanization of a monoclonal antibody that neutralizes human leukocyte interferon: a candidate therapeutic for IDDM and SLE."	
	Crow and Kirou (2004) <i>Curr. Opin. Rheumatol.</i> 16(5): 541-47, entitled "Interferon-alpha in systemic lupus erythematosus."	
	Crow (2003) <i>Arthritis Rheum.</i> 48(9): 2396-2401, entitled, "Interferon-alpha: a new target for therapy in systemic lupus erythematosus?"	
	Devendra and Eisenbarth (2004) <i>Clin. Immunol.</i> 111(3): 225-233, entitled "Interferon alpha—a potential link in the pathogenesis of viral-induced type I diabetes and autoimmunity."	
	Exley <i>et al.</i> (1984) <i>J. Gen. Virol.</i> 65 (12): 2277-2280, entitled "A comparison of the neutralizing properties of monoclonal and polyclonal antibodies to human interferon alpha."	
	Files <i>et al.</i> (1998) <i>J. Interferon Cytokine Res.</i> 18(12): 1019-24, entitled "A novel sensitive and selective bioassay for human type I interferons."	
	Fish <i>et al.</i> (1989) <i>J. Interferon Res.</i> 9(1): 97-114, entitled "The role of three domains in the biological activity of human interferon-alpha."	
	Foster <i>et al.</i> (2004) <i>J. Immunol.</i> 173(3): 1663-70, entitled "IFN-alpha subtypes differentially affect human T cell motility."	
	Green <i>et al.</i> (2004) <i>Cytokine</i> 26(5): 209-16, entitled "IgG-derived Fc down-regulates virus-induced plasmacytoid dendritic cell (pDC) IFN $\alpha$ production."	
	Gringeri <i>et al.</i> (1999) <i>J. AIDS Hum. Retrovirol.</i> 20(4): 358-70, entitled "Active anti-interferon-alpha immunization: a European-Israeli, randomized, double-blind, placebo-controlled clinical trial in 242 HIV-1-infected patients (the EURIS study)."	
	Gringeri <i>et al.</i> (1996) <i>J. AIDS Hum. Retrovirol.</i> 13(1): 55-67, entitled "Absence of clinical, virological, and immunological signs of progression in HIV-1-infected patients receiving active anti-interferon-alpha immunization: a 30-month follow-up report."	
	Gringeri <i>et al.</i> (1995) <i>Cell. Mol. Biol. (Noisy-le-grand)</i> 41(3): 381-87, entitled "Anti-alpha interferon immunization: safety and immunogenicity in asymptomatic HIV positive patients at high risk of disease progression."	
	Huang <i>et al.</i> (1994) <i>Immunity</i> 1: 469-478, entitled "Islet Expression of IFN- $\alpha$ Precedes Diabetes in Both the BB Rat and Streptozotocin-treated Mice"	
	Hussain <i>et al.</i> (1997) <i>J. Interferon Cytokine Res.</i> 17(9): 559-66, entitled "Both variant forms of interferon-alpha4 gene (IFNA4a and IFNA4b) are present in the human population."	

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	Isenberg and Leckie (2002) <i>Scand. J. Rheumatol.</i> 31(4): 187-91, entitled "Biological treatments for systemic lupus erythematosus."	
	Kirou <i>et al.</i> (2004) <i>Arthritis &amp; Rheumatism</i> 50(12): 3958-3967, entitled "Coordinate overexpression of interferon-alpha-induced genes in systemic lupus erythematosus."	
	Mohity <i>et al.</i> (2003) <i>J. Immunol.</i> 171(7): 3385-93, entitled "IFN-alpha skews monocyte differentiation into Toll-like receptor 7-expressing dendritic cells with potent functional activities."	
	Morser <i>et al.</i> (1981) <i>J. Gen. Virol.</i> 53(2): 257-65, entitled "Production and screening of cell hybrids producing a monoclonal antibody to human interferon-alpha."	
	Noll <i>et al.</i> (1989) <i>Biomed. Biochim. Acta</i> 48(1): 165-76, entitled "Production and characterization of four monoclonal antibodies specific for human interferon-alpha-1 and -alpha-2."	
	Overall and Hertzog (1992) <i>Mol. Immunol.</i> 29(3): 391-99, entitled "Functional analysis of interferon-alpha subtypes using monoclonal antibodies to interferon-alpha4a-subtype reactivity, neutralisation of biological activities and epitope analysis."	
	Reyes and Klimpel (1987) <i>Transplantation</i> 43(3): 412-416, entitled "Interferon alpha/beta synthesis during acute graft-versus-host disease."	
	Rönnblom <i>et al.</i> (2003) <i>Autoimmunity</i> 36(8): 463-472, entitled "Role of Natural Interferon-α Producing Cells (Plasmacytoid Dendritic Cells) in Autoimmunity."	
	Rönnblom and Alm (2001) <i>Trends Immunol.</i> 22(8): 427-31, entitled "An etiopathogenic role for the type I IFN system in SLE."	
	Rönnblom and Alm (2001) <i>J. Exp. Med.</i> 194(12): F59-63, entitled "A pivotal role for the natural interferon alpha-producing cells (plasmacytoid dendritic cells) in the pathogenesis of lupus."	
	Santiago-Raber <i>et al.</i> (2003) <i>J. Exp. Med.</i> 197(6): 777-88, entitled "Type-I interferon receptor deficiency reduces lupus-like disease in NZB mice."	
	Schattner <i>et al.</i> , (1988) "Review: Interferons and autoimmunity". <i>Am. J. Med. Sci.</i> 295:532-544.	
	Skurkovich <i>et al.</i> (1997) <i>Cytokine</i> 9(11): 899 (meeting abstract), entitled "The use of antibodies to cytokines (anti-IFN-α, anti-IFN-γ, anti-TNF-α) is an effective method for the treatment of rheumatic diseases-rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), psoriatic arthritis (PA), and Behcet's syndrome (BS)."	
	Skurkovich <i>et al.</i> (2002) <i>Med. Hypotheses</i> 59(6): 770-80, entitled "Anticytokine therapy—new approach to the treatment of autoimmune and cytokine-disturbance diseases."	
	Staehelin <i>et al.</i> (1981) <i>Proc. Nat'l. Acad. Sci. USA</i> 78(3): 1848-52, entitled "Production of hybridomas secreting monoclonal antibodies to the human leukocyte interferons."	
	Stewart (2003) <i>Cytokine Growth Factor Rev.</i> 14(2): 139-54, entitled "Neutralizing interferon alpha as a therapeutic approach to autoimmune diseases."	
	Tsukui <i>et al.</i> (1986) <i>Microbiol. Immunol.</i> 30(11): 1129-39, entitled "A monoclonal antibody with broad reactivity to human interferon-alpha subtypes useful for purification of leukocyte-derived interferon."	

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Sheet 5 of 5	Attorney Docket No: AGT.10006NP												

	Vancová <i>et al.</i> (2000) <i>J. Interferon Cytokine Res.</i> 20(5): 455-61, entitled "The carboxyterminal domains of human IFN-alpha2 and IFN-alpha8 are antigenically homologous."	
	Vilcek <i>et al.</i> , (1986). In <i>Aids: The epidemic of karposi's sarcoma and opportunistic infections. "The Role of Interferon in AIDS,"</i> A.E. Friedman-Klein & L.J. Laubenstein, eds. Masson Publishing, New York, New York, 193-198.	
	Viscomi <i>et al.</i> (1999) <i>J. Interferon Cytokine Res.</i> 19(4): 319-326, entitled "Antigenic characterization of recombinant, lymphoblastoid, and leukocyte IFN-alpha by monoclonal antibodies."	
	Zagury <i>et al.</i> (1999) <i>Biomed Pharmacother.</i> 53(2): 90-92, entitled "Anti-IFN alpha immunization raises the IFN alpha-neutralizing capacity of serum—an adjuvant to antiretroviral tritherapy."	

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/Gyan Chandra/

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